REMARKS

Prior to the present amendment, claims 1-5 were pending. By this amendment, applicants have canceled claims 1-5, and added new claims 6-20. Accordingly, claims 6-20 are currently pending.

In the Office Action dated February 10, 2004, claims 1-5 were rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement. The examiner contends that the method does not appear to work as claimed. According to the examiner, it is unclear how the binding sites on the transglutaminase IgA or IgG are prevented from being saturated with the labeled antigen. The examiner asserts that if the binding sites are saturated, they would not be available to bind to the unlabeled, immobilized antigen. Therefore, according to the examiner, no label would be detected, leading to a false negative result.

The examiner further states that the specification recites an example where the assay is conducted. However, the examiner states that it cannot be determined whether the example is theoretical or the assay was actually conducted.

Applicants respectfully disagree with the examiner. Applicants would like to point out to the examiner that a limit of detection is inherent in any type of assay. In fact, such a low amount of antibody in the sample may not be statistically significant to indicate celiac disease, and thus, would not be considered a false negative result as the examiner asserts. What is important to know is the amount which has clinical significance. Therefore, the claimed invention is enabled.

To support applicants' position that the claimed invention is enabled, applicants would like to bring to the examiner's attention the Sorell et al. article published on March 16, 2002 (after the priority date of the claimed invention) in the journal, *Lancet* (volume 359, pages 945-946). Both inventors of the claimed invention are listed as authors of the Sorell et al. article. For the examiner's convenience, a copy of the Sorell et al. article is enclosed as exhibit 1.

In Sorell et al., the claimed immunochromatographic system was used to determine the presence of celiac disease in fifty untreated celiac patient and forty non-celiac patients. All fifty patients with celiac disease tested positive with the claimed immunochromatographic system. Further, all forty non-celiac patients tested negative with the claimed immunochromatographic system. See the paragraph bridging page 945 and 946 of Sorell et al.

Thus, the data presented in Sorell et al. supports applicants' position that the claimed invention is enabled. Further, the experiment reported in Sorell et al. is similar to the example recited in the specification. Accordingly, applicants respectfully request that the rejection under §112 allegedly for lack of enablement be withdrawn.

Claims 1-5 were rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite for various reasons. Applicants have canceled claims 1-5, and have added new claims 6-20. In view of applicants' amendments to the claims and the above argument that the claimed invention is enabled, applicants respectfully request that the §112 rejection be reconsidered and withdrawn.

Support for Amendments to the Specification

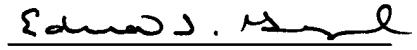
Support for the new paragraph on page 5, starting at line 6 can be found in the specification and claims as originally filed, *inter alia*, page 4, third paragraph and claim 1.

Support for Amendments to the Claims

Support for new claims 6-20 can be found in the specification and claims as originally filed, *inter alia,* page 4, third paragraph to page 5, fourth paragraph, claims 1-5, and the examples.

In view of the above amendments and remarks, allowance of pending claims 6-20 is earnestly requested. If the examiner has any questions regarding this amendment, the examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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